< Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	John W. Darrah	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	01 C 1914	DATE	3/19/2002
CASE TITLE	ABBOTT LABS vs. NOVOPHARM		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ☐ Status hearing[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ General Rule 21 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] Enter Memorandum Opinion and Order. Novopharm's motion for summary judgment of Noninfringement is granted. Status hearing is set for 3/27/02 at 9:00 a.m.

(11) ■ [For further detail see order attached to the original minute order.]

	No notices required, advised in open court.		number of notices	Document Number
	No notices required.		MAR 20 2002	
	Notices mailed by judge's staff.		date docketed	
	Notified counsel by telephone.			
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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ABBOTT LABORATORIES, an Illinois corporation; FOURNIER INDUSTRIE ET SANTÉ, a French corporation;and LABORATOIRES FOURNIER S.A., a French corporation,	)	**Nos. 00 C 2141, 00 C 5094, and 01 C 1914**
Plaintiffs,	)	
v.	)	
NOVOPHARM LIMITED, a corporation of the dominion of Canada; and TEVA PHARMACEUTICAL INDUSTRIES LTD., an Israeli corporation,	)	**Judge John W. Darrah**
Defendants.	)	

MEMORANDUM OPINION AND ORDER

Defendant, Novopharm, filed an Abbreviated New Drug Application ("ANDA") seeking the Food and Drug Administration's ("FDA") approval to market a generic micronized fenofibrate product in three dosage forms. Subsequently, Fournier, the owner of the Curtet Patent, and Abbott, Fournier's exclusive licensee under the Curtet Patent, filed the present actions for each of Novopharm's three proposed dosage forms, alleging that the process described in Novopharm's ANDA and the products produced by that process would infringe the Curtet Patent. The three lawsuits were consolidated. Presently before the Court is Novopharm's Motion for Summary Judgment of Noninfringement.

FACTS

The Curtet Patent has 12 claims. (Def.'s 56.1(a)(3) Statement ¶ 20). Claims 1 and 10 are the only independent claims of the Curtet Patent. Claims 2-9 and 11-12 depend ultimately from

claim 1. (Id., at ¶¶ 21-22).

Claim 1 of the Curtet Patent, as originally filed, stated :

> A therapeutic composition, presented in the form of gelatin capsules, which is useful especially in the oral treatment of hyperlipidemia and hypercholesterolemia, the said composition containing fenofibrate and a solid surfactant which have been co-micronized. (Def.'s 56.1(a)(3) Statement ¶ 75).

During the Patent's prosecution, the United States Patent and Trademark Office ("PTO") issued an "Office Action", rejecting claim 1 under 35 U.S.C. § 103 as being obvious over Schonafinger *et al.* in view of Schonafinger and Grouiller. (Id, at ¶¶ 76-77).

In July 1989, Fournier submitted an amendment in response to the Office Action. The amendment added the present limitation of "a co-micronized mixture of particles". (Id., at ¶¶ 78-79).

Fournier distinguished the cited prior art from the claimed invention, as amended, on the ground that the prior art did not teach or suggest co-micronization of fenofibrate and a solid surfactant such that co-micronization as claimed resulted in an improvement, namely improved bioavailability. (Def.'s 56.1(a)(3) Statement ¶ 82). In response to the Office Action, Fournier explained to the PTO that "none of the [cited] references alone in any combination thereof teaches or suggests co-micronization of a mixture of fenofibrate and a solid surfactant." (Id., at ¶ 83). Fournier also explained that "none of the [cited] references alone or in any combination thereof teaches or suggests ... that by co-micronizing said mixture a lower daily dosage may be administered because the bioavailability of fenofibrate is significantly and unexpectedly increased." (Id., at ¶ 84).

The amendment also stated that "Groullier et al. [does not] teach or suggest co-micronization of a mixture of fenofibrate with a solid surfactant to produce particles having a diameter of less than 15 μm." (Def.'s 56.1(a)(3) Statement ¶ 85). It further differentiated Schonafinger, stating that

"Schonafinger ('743), thus, does not teach or suggest co-micronization of fenofibrate with a solid surfactant." (Id., at ¶ 86). Fournier stated, "none of [the references cited in the Office Action] alone or in any combination thereof teaches or suggests co-micronization of a mixture of fenofibrate and a solid surfactant, wherein the particles in said co-micronized mixture have mean diameter less than 15 μm." (Id., at ¶ 88).

The amendment also addressed dissolution, stating that it could "be seen in all instances fenofibrate in the co-micronized mixture dissolves about 20-25% faster than fenofibrate that is micronized prior to mixing with micronized solid surfactant." (Def.'s 56.1(a)(3) Statement ¶ 91). Fournier stated that "none of [the cited references] teach or suggest that co-micronizing fenofibrate with a solid surfactant will increase the rate at which fenofibrate dissolves compared to the rate at which micronized fenofibrate mixed with micronized solid surfactant dissolves...." (Id., at ¶ 93).

Following the amendments and above arguments, the PTO allowed all of the claims. (Def.'s 56.1(a)(3) Statement ¶ 96).

Claim 1 of the Curtet Patent states, in its entirety:

> A therapeutic composition, which is presented in the form of gelatin capsules and which is useful especially in the oral treatment of hyperlipidemia and hypocholesterolemia, said composition containing a co-micronized mixture of particles of fenofibrate and a solid surfactant, wherein the mean particle size of said co-micronized mixture is less than 15 μm. (Id., at ¶ 23).

Claim 8 of the Curtet Patent, which depends on claim 1, states:

> A method for the manufacture of a therapeutic composition according to claim 1, which comprises:
> (i) intimately mixing and then co-micronizing the fenofibrate and solid surfactant,
> (ii) adding lactose and starch to the mixture obtained,
> (iii) converting the whole to granules in the presence of water,

(iv) drying the granules until they contain no more than 1% of water,
(v) grading the granules,
(vi) adding polyvinylpyrrolidone and magnesium stearate, and
(vii) filling gelatin capsules. (Def.s 56.1(a)(3) Statement ¶ 24).

Claim 10 of the Curtet Patent states:

> A method for improving the bioavailablilty of fenofibrate *in vivo*, which comprises co-micronization of the fenofibrate and a solid surfactant, the said co-micronization being carried out by the micronization of a fenofibrate/solid surfactant mixture until the particle size of the powder obtained is less than 15 μm. (Def.'s 56.1(a)(3) Statement ¶ 26).

The Curtet Patent states a dosage form of one 300 mg fenofibrate gelatin capsule had been proposed. (Def.'s 56.1(a)(3) Statement ¶ 36). The Curtet Patent also states:

> It is known that micronization of an active principle is capable of improving the dissolution of the said active principle in vivo, and hence its bioavailability. It is known that the addition of a surfactant excipient to a formulation of an active principle is capable of improving absorption and consequently the bioavailability of the said active principle. (Id., at ¶ 37; Curtet Patent).

The only "active principle" discussed in the Curtet Patent is fenofibrate. (Id., at ¶ 38).

The Curtet Patent states that it is the "co-micronization of fenofibrate and a solid surfactant (i.e., the micronization of an intimate mixture of fenofibrate and a solid surfactant) makes it possible to improve the bioavailability of the fenofibrate to a significantly greater extent than that which would be achieved either by adding a surfactant [to fenofibrate], or by micronizing the fenofibrate on its own, or by intimately mixing the separately micronized fenofibrate and surfactant." (Def.'s 56.1(a)(3) Statement ¶¶ 43-44; Curtet Patent).

The Curtet Patent states that the surfactant "will be selected from solid surfactants so that it can be co-micronized with fenofibrate." (Def.'s 56.1(a)(3) Statement ¶ 56). Sodium lauryl sulfate

("SLS") is the only example of a solid surfactant disclosed in the Curtet patent. (Id., at ¶ 58). "The micronization of the fenofibrate and the solid surfactant will be advantageously carried out in an accelerated air-jet mill...." Furthermore, "[t]o obtain a powder which can be formulated into gelatin capsules .... lactose ... may be added to the co-micronizate of fenofibrate and solid surfactant." (Curtet Patent).

The Curtet Patent sets forth "a method for the preparation of a therapeutic composition containing fenofibrate and a solid surfactant is recommended which comprises: (i) intimately mixing and then co-micronizing the fenofibrate and solid surfactant, (ii) adding lactose and starch to the mixture obtained ...." It also provides "Preparative Examples" to aid in understanding the patent and to show that the patent is non-obvious. For example, "Preparation I" states: "The fenofibrate/sodium lauryl-sulfate mixture is co-micronized in an air-jet micronizer to give a powder with a medium particle size of 3 μm. The lactose and the starch are then added to this powder ...." (Def.'s 56.1(a)(3) Statement ¶¶ 45-46, 60; Curtet Patent).

In December 1999, Fournier filed for reexamination of the Curtet Patent. (Def.'s 56.1(a)(3) Statement ¶ 97). The request for reexamination stated that an article entitled, "Microbroyage et Dissolution", authored by Georges Boullay, raised a substantial new question of the patentability of the claims of the Curtet Patent. (Id., at ¶ 98). The PTO granted reexamination in early 2000. (Id., at ¶ 99).

During the reexamination, Fournier stated, "unlike fenofibrate which exhibits unexpectedly rapid dissolution when co-micronized with surfactant compared with fenofibrate micronized alone, [other fibrates] show no statistically significant increase in dissolution." (Def.'s 56.1(a)(3) Statement ¶ 102). A declaration by Philippe Reginault, one of the inventors, submitted by Fournier, compared

"co-micronized fibrates" with "the corresponding fibrate that was first micronized and then mixed with a micronized solid surfactant". (Id., at ¶ 105). In May 2001, the PTO concluded the reexamination proceeding and upheld the patent. (Id., at ¶ 106).

Descriptions of the process steps that Novopharm employs for manufacturing all three dosage forms of its proposed products have been submitted to the FDA in connection with Novopharm's NDA. (Def.'s 56.1(a)(3) Statement ¶ 108). According to Novopharm's process, fenofibrate is first pre-micronized on its own and in the absence of any other ingredient. (Id., at ¶ 109). The pre-micronized fenofibrate is then dry mixed with lactose monohydrate, pregelatinized starch, croscarmellose sodium and crosspovidone. (Id., at ¶ 110).

Separately, for the above dry mixing step, povidone and sodium lauryl-sulfate are dissolved in water to form a granulating solution. (Def.'s 56.1(a)(3) Statement ¶ 111). The granulating solution is then added to the dry fenofibrate mixture. (Id., at ¶ 112). The mixture of the granulating solution and the dry fenofibrate mixture resulting from the previous step is subjected to a wet granulation process involving the addition of more water and thorough mixing. (Id., at ¶ 113).

Following wet granulation, the mixture is dried, weighed, and assessed for "loss on drying". (Def.'s 56.1(a)(3) Statement ¶ 114). The dried, granulated mixture is then dry blended with additional croscarmellose sodium, crosspovidone, and magnesium stearate to produce granules that can pass through a #16 mesh screen. (Id., at ¶ 115). The granulated mixture is then blended again, weighed, and stored for eventual encapsulation into gelatin capsules. (Id., at ¶ 117).

LEGAL STANDARDS

Summary judgment is proper if "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue as to any

material fact." Fed. R. Civ. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). All the evidence and the reasonable inferences that may be drawn from the evidence are viewed in the light most favorable to the nonmovant. *Miller v. American Family Mutual Ins. Co.*, 203 F.3d 997, 1003 (7th Cir. 2000). Summary judgment may be granted when no "reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

A patent infringement analysis consists of two steps. In the first step, the meaning and scope of the patent claims asserted to be infringed are determined. This is commonly referred to as claim construction. The second step entails proving the infringement by comparing the properly construed claims to the device accused of infringing. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (*Markman*).

A. Claim Construction

In construing the claims of a patent, the court reviews the extrinsic evidence of record. This evidence includes the claims of the patent, the specifications, and the prosecution history. *See Bell Atlantic Network Serv., Inc. v. Covad Communications Group, Inc.*, 262 F.3d 1258, 1267 (Fed. Cir. 2001) (*Covad*).

Generally, all of the terms in a patent claim are given their plain, ordinary, and accustomed meaning to one of ordinary skill in the relevant art. *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001) (*Rexnord*). Unless compelled to do otherwise, a court should give a claim term the full range of its ordinary meaning as understood by one of ordinary skill in the relevant art. *Rexnord*, 274 F.3d at 1342. Dictionaries and technical treatises, while extrinsic evidence, may also be considered along with the intrinsic evidence when determining the ordinary meaning of claim

terms. *Covad*, 262 F.3d at 1267.

Once the plain meaning of a disputed claim term is ascertained, the court must examine the written description and any drawings to confirm that the patentee's use of the disputed term is consistent with the meaning given to such term by the court. *Rexnord*, 274 F.3d at 1342. The written description and any drawings are reviewed to determine if the patentee chose to set forth an explicit definition that is different in scope from that of the ordinary meaning. In addition, the court examines the written description and drawings to determine whether the preferred embodiment falls within the scope of a construed claim because a claim construction that would exclude the preferred embodiment 'is rarely, if ever, correct and would require highly persuasive evidentiary support'. *Rexnord*, 274 F.3d at 1342, quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). Furthermore, the written description and drawings are reviewed to determine whether the patentee disclaimed any subject matter or has otherwise limited the scope of the claims. *Rexnord*, 274 F.3d at 1342.

Lastly, the court reviews the prosecution history because a statement made during the prosecution of a patent may affect the scope of the invention and the meaning of the claims. *Covad*, 262 F.3d at 1268.

B. Infringement

"In order to prove infringement, a patentee must show that every limitation of the claims asserted to be infringed is found in the accused device." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1565 (Fed. Cir. 1997). As a matter of law, an accused device cannot infringe if even a single limitation is not satisfied. *Digital Biometrics, Inc. v. Identix, Inc.*, 149 F.3d 1335, 1349 (Fed. Cir. 1998).

Infringement is proved either literally or under the doctrine of equivalents. *See Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir.1998). "To establish literal infringement, every limitation set forth in a claim must be found in the accused product, exactly." *Southwall Technologies, Inc. v. Cardinall IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995).

Under the doctrine of equivalents, an accused device infringes only if it possesses all of the limitations of the claim either literally or equivalently. *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998). The "doctrine of equivalents must be applied to individual elements of the claim, not to the invention as a whole." *Warner-Jenkinson v. Davis*, 570 U.S. 17, 29 (1997) (*Davis*). Furthermore, application of the doctrine cannot be used to erase limitations from the claim. *Davis*, 570 U.S. at 29. The differences between the accused device and the claim limitation must be "insubstantial" to possess an equivalent claim limitation. *Desper*, 157 F.3d at 1338. This analysis generally turns on whether the accused device performs substantially the same function in substantially the same way to achieve substantially the same result. *Alpex Computer Corp. v. Nintendo Co.*, 102 F.3d 1214, 1222 (1996).

Another factor affecting the issue of infringement is the doctrine of prosecution history estoppel. The doctrine of prosecution history estoppel prohibits the application of equivalents and precludes a patentee from obtaining coverage under the doctrine of equivalents of subject matter that was relinquished during the prosecution of the patent. *General Elec. Co. v. Nintendo Co.*, 179 F.3d 1350, 1362 (Fed. Cir. 1999).

Prosecution history estoppel occurs as a result of arguments made during prosecution of the patent that show a clear and unmistakable surrender of subject matter through amendments made to overcome patentability rejections (*Bayer AG v. Elan Pharmaceutical Research Corp.*, 212 F.3d

1241, 1251 (Fed. Cir. 2000)) or through unequivocal arguments or assertions made during patent prosecution (*Desper Prods., Inc. v. Qsound Labs*, 157 F.3d 1325, 1338 (Fed. Cir. 1998) and/or reexamination (*Intermatic Inc. v. Lamson & Sessions Co.*, 273 F.3d 1355, 1366 (Fed. Cir. 2001). The determination of what subject matter was surrendered is an objective one, measured from the vantage point of what a competitor reasonably would conclude the patentee had relinquished in order to secure the patent. *Augustine Medical, Inc. v. Gaymar Indus., Inc.*, 181 F.3d 1291, 1299 (Fed. Cir. 1999).

ISSUES

A. Claim Construction

The parties dispute the construction of the term "co-micronized". Plaintiffs argue that the term should be given its "ordinary meaning" of "micronized with or together". Defendant argues that the term should be construed narrowly to mean that "fenofibrate and a solid surfactant have been micronized together and in the absence of any other excipients".

In essence, the parties do not disagree as to the common meaning of the term "co-micronized". Both parties agree that the common meaning is construed to mean "micronized with or together". This common meaning is supported by the definitions of the parts of the word. "Co-" is defined the same as "con-" -- "a prefix meaning with or together". Dorland's Illustrated Medical Dictionary 368, 389 (29th ed. 2000). "Micronize" is defined as "to reduce to a fine powder; to reduce to particles a micron in diameter". Dorland's Illustrated Medical Dictionary 1112 (29th ed. 2000). Accordingly, the ordinary meaning of the term "co-micronized" would be "to reduce to a fine powder [micronize] with or together".

Defendant argues that the claim language, specification, and prosecution history support a

more narrow definition to include that only fenofibrate and a solid surfactant have been micronized together in the absence of any other excipients. Plaintiff argues that Defendant is impermissibly reading a limitation into the claim from the specification.

The term "co-micronize" or a derivative thereof, i.e., co-micronizing, are used in multiple claims, including claims 1, 8, and 10. In each of these claims, a mixture of fenofibrate and a solid surfactant are micronized together. Claim 10 also refers to the micronization of a "fenofibrate/solid surfactant mixture". No other materials or excipients are identified as being part of and of these mixtures.

The term "co-micronize" or its derivatives are also used throughout the specification. For example, the specification states, in pertinent part, that it "has now been discovered that the co-micronization of fenofibrate and a solid surfactant (i.e., the micronization of an intimate mixture of fenofibrate and a solid surfactant) makes it possible to improve the bioavailability ... than that which would be achieved either by adding a surfactant, or by micronizing the fenofibrate on its own, or by intimately mixing the separately micronized fenofibrate and surfactant." Through this language, Plaintiff distinguished its co-micronized mixture of fenofibrate and a solid surfactant from mixtures obtained by adding a surfactant to fenofibrate, or micronizing fenofibrate by itself, and/or mixing separately micronized fenofibrate and surfactant. By distinguishing its co-micronized mixture from these types of mixtures, Plaintiff's co-micronized mixture cannot include such mixtures. *See O.I. Corp. v. Tekmar Co.*, 115 F.3d 1576, 1581 (Fed. Cir. 1997) (description that distinguished claim over prior art narrowed construction of disputed term). In all of the examples for preparing the product, fenofibrate and a solid surfactant are the only materials micronized together. After the co-micronization, other excipients are added.

During the prosecution of the Curtet Patent and the subsequent reexamination, Plaintiff repeatedly alleged that prior art did not teach or suggest co-micronization of a mixture of fenofibrate and a solid surfactant. Furthermore, Plaintiff stated that fenofibrate in the co-micronized mixture dissolves faster than fenofibrate dissolves when micronized fenofibrate is mixed with micronized solid surfactants. The prosecution history demonstrates that Plaintiff distinguished its claims, in part, on the fact that fenofibrate and a solid surfactant would be micronized together. In every instance, no other materials are included in this co-micronization. Furthermore, fenofibrate and a solid surfactant are the only materials identified in reference to the "co-micronized mixture".

The above demonstrates that Plaintiff micronizes, together, fenofibrate and a solid surfactant. The claims, description, and prosecution history do not indicate that anything other than fenofibrate and a solid surfactant are micronized. Furthermore, the description and prosecution history indicate that one of the distinguishing elements of this Patent is the co-micronization of a fenofibrate/solid surfactant mixture. No other excipient is identified as part of this mixture.

In light of the above, one skilled in the art reading the claims, description, and prosecution history would conclude that the term "co-micronize" in claims 1 and 10 does not encompass co-microzination of excipients other than fenofibrate and a solid surfactant.

Based on the above, the term "co-micronized" is construed to mean that fenofibrate and a solid surfactant have been micronized together in the absence of other excipients.

Defendant also seeks to limit the construction of the phrase "fenofibrate/solid surfactant mixture" in claim 10 to exclude any other ingredients other than fenofibrate and solid surfactant. Plaintiff does not dispute this construction.

"Mixture" is defined as "a combination of different drugs or ingredients". Dorland's

Illustrated Medical Dictionary 1122 (29th ed. 2000). Accordingly, a fenofibrate/solid surfactant mixture would be defined as a combination of fenofibrate and solid surfactant. No other materials are included in the description of the mixture; and the claims, patent description, and prosecution history support the conclusion that no other materials are included in the mixture.

Defendant also seeks to limit the phrase "mixture of particles of fenofibrate and a solid surfactant" to mean a "mixture wholly of fenofibrate and a solid surfactant, to the exclusion of any other excipients". Plaintiff opposes such construction, arguing that the phrase is properly construed to mean "a resultant mixture composed of (but not necessarily wholly of) particles that are composed of (but not necessarily wholly of) fenofibrate and a solid surfactant".

"Of" is defined as "a function word to indicate the material, parts, or elements composing something". Webster's Third New Int'l Dictionary 1565 (3rd ed. 1986).

In a similar claim, the Eastern District Court of New York construed the language 'net supporters made of PFA, FEP or EPE' to mean that the 'net supporters must be made wholly of PFA, FEP or EPE, and cannot include any other fluorocarbon resin...' *Pall Corp. v. PTI Tech. Inc.*, 259 F.3d 1383, 1390 (Fed. Cir. 2001) (*Pall*), quoting *Pall Corp. v. PTI Techs.*, Nos. CV-97-1134, CV-98-2871 (E.D.N.Y Dec. 22, 1999). On appeal, the parties did not dispute this claim construction, and the Federal Circuit "agree[d] with the district court's claim construction requiring the net supporters to be made of 100% of one of the recited ... resins." *Pall*, 259 F.3d at 1390.

In light of the claim language, and the patent description and prosecution history discussed above, the phrase "mixture of particles of fenofibrate and a solid surfactant" means a "mixture of particles wholly of fenofibrate and a solid surfactant".

B. Infringement

1. Literal Infringement

In order to establish literal infringement, Plaintiff must demonstrate that every limitation in a claim is exactly found in the accused device. *Southwall*, 54 F.3d at 1576. As to claim one, the parties do not dispute that fenofibrate and a solid surfactant are not micronized together in the absence of other excipients in Defendant's product. Accordingly, Defendant does not literally infringe either claim 1 or 10 of the Curtet Patent.

2. Doctrine of Equivalents

Defendant first argues that Plaintiff is estopped from asserting the doctrine of equivalents as to claim 1 and 10's co-microzination limitation.

During the prosecution of the Curtet Patent, Plaintiff amended claim 1, changing the original phrase of "the said composition containing fenofibrate and a solid surfactant which have been co-micronized" to state "said composition containing a co-micronized mixture of particles of fenofibrate and a solid surfactant, wherein the mean particle size of said co-micronized mixture is less than 15 μm." Plaintiff distinguished the prior art from the claimed invention, in part, on the ground that prior art did not teach or suggest co-micronization of fenofibrate and a solid surfactant such that the co-micronization resulted in an improvement in bioavailability. Plaintiff further stated that "none of the [cited] references alone or in combination thereof teaches or suggests ... that co-micronizing said mixture a lower daily dosage may be administered because the bioavailability of fenofibrate is significantly and unexpectedly increased."

These arguments clearly demonstrate that Plaintiff distinguished its invention from prior art because of the increase in bioavailability obtained through co-micronization of fenofibrate and a

solid surfactant.

In the Curtet Patent Plaintiff addressed this increase in bioavailability and distinguished its product and process from those achieved by adding a surfactant or by micronizing the fenofibrate on its own or by intimately mixing the separately micronized fenofibrate and surfactant.

During the reexamination of the Curtet Patent, Plaintiff further distinguished co-micronization of fenofibrate and a solid surfactant to fenofibrate that is micronized alone when discussing dissolution rates in order to distinguish the Curtet Patent.

Based on the arguments made during the prosecution of the patent as to increased bioavailability, patent language as to bioavailability, and the arguments made during reexamination, a competitor would reasonably conclude that Plaintiff relinquished a product and process that involved either adding a surfactant by itself or by micronizing the fenofibrate on its own or by intimately mixing the separately micronized fenofibrate and surfactant.

In the instant case, it is undisputed that Defendant pre-micronizes fenofibrate by itself. The above demonstrates that Plaintiff specifically distinguished its co-micronized product and co-micronization process from those obtained from micronizing fenofibrate by itself, as done by Defendant. Accordingly, Plaintiff cannot establish infringement under the doctrine of equivalents for claims 1 or 10. *See Cole v. Kimerbly-Clark Corp.*, 102 F.3d 524, 532 (Fed. Cir. 1997) (affirming district court's finding that defendant's accused products did not infringe under the doctrine of equivalents based upon the patent's prosecution history during which plaintiff relinquished coverage

to obtain its patent); *Builders Concrete, Inc. v. Bremerton Concrete Products Co.*, 757 F.2d 255, 260 (Fed. Cir. 1985).

CONCLUSION

For the forgoing reasons, Novopharm's Motion for Summary Judgment of Noninfringement is granted.

Dated: March 19, 2002

JOHN W. DARRAH
United States District Judge